

REMARKS

This Amendment is in response to the Notice of Non-Complaint Amendment dated May 9, 2003. Consideration thereof is respectfully requested.

The applicant appreciates the examiner's thorough examination of the subject application and requests reexamination and reconsideration of the subject application in view of the preceding amendments and the following remarks.

The examiner raises concerns with the drawing previously submitted in the subject application. In response to these concerns, applicant submits herewith a replacement FIG. 1. Applicant has amend FIG. 1 to include a reference to element 20 (*See Applicant's specification, page 3, lines 36-37*). No new matter has been added.

The examiner objects to the specification of the subject application. In response to these objections, applicant submits herewith a "Title", "Technical Field" portion, "Background" portion, "Summary" portion, and "Description of Drawings" portion. No new matter has been added.

The examiner rejects claim 4 under 37 CFR 1.74(c) as being in improper form because a multiple dependant claim cannot depend upon another multiple dependant claim. In response to this rejection, applicant has cancelled claims 1-4 and provided amended claims 5-16 that satisfy 37 CFR 1.74(c).

The examiner rejects claims 1-4 under 35 USC §112 as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. In response to this rejection, applicant has cancelled claims 1-4 and provided amended claims 5-16 that satisfy 35 USC §112

The examiner rejects claims 1-4 under 35 USC §103(b) based on the combination of the teachings of Foley et al (U.S. Patent No. 6,021,343) and Hoborn et al (U.S. Patent No. 4,321,925).

The applicant claims (in, for example, new claim 5) "[an] untethered, active instrument for determining a position in a navigation system that assists in surgical operations, comprising a power supply including one or more solar cells". *Emphasis Added*.

Applicant respectfully asserts that the combination of these two references do not teach the applicant's claimed *untethered* invention. Accordingly, applicant respectfully asserts that the combination of the teachings of Foley and Hoborn are not a proper basis for a 35 USC §103(b) rejection, as the combination does not teach each and every element of the applicant's claimed invention.

The use of active instruments during surgical procedures is becoming increasingly popular. As certain instruments (e.g., endoscopes, bronchoscopes, and biopsy needles) are used in an invasive manner, these devices must be properly sterilized in order to minimize the risk of infections. Accordingly, strict cleaning and sterilization procedures must be employed to minimize the chance of patient infection.

Complicating this cleaning and sterilization procedure is the fact that active devices are tethered to an external device. For example, an endoscope may include a plurality of optical positioning sensors or LED's at its base (i.e., the non-invasion portion of the scope) which are used in conjunction with a navigation system to determine the position of the endoscope within a patient's abdominal cavity. In order to power these sensors or LED's, the endoscope is tethered via a cable to the navigation system. This tether may also provide power to other devices on the endoscope, such as a surgical workspace illuminator. This tether presents multiple problems for the surgeon or technician using the device, as (1) the tether impedes freedom of movement, and (2) the tether complicates the sterilization procedure. This is especially true when you consider that a lot of these devices are sterilized in autoclaves.

The applicant's invention addresses these problems through the use of one or more solar cells (as opposed to a tether) that power the active device. This, in turn, reduces the complications associated with sterilizing the device and eliminates the mobility restriction imposed by the use of a tethered device.

As stated above, the examiner rejects the applicant's claimed invention based on the teachings of Foley in view of Hoborn. Applicant respectfully asserts that Hoborn is non-analogous art in that the Hoborn reference disclose the use of a solar cell to power a surgical glove perforation detector. What must be realized is that the device being powered in Hoborn is located in the shoe of the surgeon or technician performing the surgery. Accordingly, a person of ordinary skill in the art would not look toward the teaching of Hoborn to solve a problem

concerning a device that must be sterilized. Specifically and as stated above, the Hoborn device is located in a shoe, which includes exposed terminals that contact the floor of the operating theater and the insole of the shoe itself. Accordingly, the Hoborn device IS NOT intend or required to be sterilized, as (1) the device is not intended to contact the patient, and (2) any attempt to sterilize the device in Hoborn would most-likely result in the device being destroyed. Additionally, any attempt to minimize the exposure of the Hoborn device to non-sterile environments (i.e., the floor) would require that the Hoborn device be insulated and isolated from the floor. As clearly realizable and understandable from the Hoborn reference, this would prevent the Hoborn device from working properly. Additionally, as the Hoborn device is clearly not intended to be sterilized, the Hoborn reference actually teaches away from the applicant's easily-sterilizable claimed invention, which claims a "[an] untethered, active instrument..." .

Additionally, the Foley reference clearly teaches the use of a tethered system. (*See Foley, Fig. 1, item 161*). Further, the Hoborn reference also *inherently* teaches a system that is tethered. Specifically, the Hoborn reference concerns a glove perforation detection system in which the conductivity between a pair of terminals (*See Hoborn, fig. 5, items A & B*) is monitored. These terminals create an electrical path in which, in the event of a glove perforation, a current flows between the pair of terminals via a conductive path comprising the body of the surgeon / technician, the patient, the operating table, and the floor of the operating theater. Therefore, in the event of a perforation, a current will flow from the hand of the surgeon / technician, through the glove perforation, and into the body of the patient, thus completing the conductive path and being indicative of a glove failure. Therefore, the only way that the Hoborn system works is if the surgeon / technician is touching the patient. Accordingly, if the surgeon / technician is not touching the patient, the conductive path will never be completed, even in the event of a glove failure.

Accordingly, for the Hoborn system to function properly, the surgeon / technician is "tethered" to the patient, wherein the "tether" is the arm of the surgeon / technician and, therefore, failure by the surgeon to maintain contact with the patient renders the Hoborn device inoperable for its intended purpose, namely indicating the perforation of a surgical glove.

Accordingly, the applicant respectfully asserts that the combination of the Foley and Hoborn references do not teach each and every element of the applicant's claimed invention,

Applicant : Manfred Schmid et al.
Serial No. : 09/914,640
Filed : August 31, 2001
Page : 13 of 13

Attorney's Docket No.: 07508-033001

namely an “untethered, active instrument”. Therefore, applicant respectfully asserts that independent claims 5, 14, and 16 are patentable over the combination of the teachings of Foley and Hoborn. Additionally, applicant respectfully asserts that claims 6-13, and 15 are also allowable, as they depend either directly or indirectly upon an allowable base claim.

Applicant respectfully asserts that all claims are in condition for allowance and applicant respectfully asks that all claims be allowed.